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Darvon® Compound-65

propoxyphene hydrochloride, aspirin, phenacetin, and caffeine

Actions: Propoxyphene hydrochloride is a mild analgesic structurally related to the narcotic analgesic methadone; though propoxyphene's general pharmacologic properties are those of the narcotics as a group, it does not compare with them in analgesic potency.

The combination of propoxyphene with a mixture of aspirin, phenacetin, and caffeine (APC compound) produces greater analgesia than that produced by either propoxyphene or APC compound administered alone.

Indication: For the relief of mild to moderate pain.

Contraindication: Hypersensitivity to propoxyphene, aspirin, phenacetin, or caffeine.

Warnings: ***C.N.S. Additive Effects and Overdosage*—Propoxyphene in combination with alcohol, tranquilizers, sedative-hypnotics, and other central-nervous-system depressants has additive depressant effects, and the patient should be so advised. Patients taking this drug should be warned not to exceed the dosage recommended by their physician. Toxic effects and fatalities have occurred following overdoses of propoxyphene alone and in combination with other central-nervous-system depressants. The majority of these patients have had previous histories of emotional disturbances or suicidal ideation or attempts as well as histories of misuse of tranquilizers, alcohol, or other C.N.S.-active drugs. Caution should be exercised in prescribing unnecessarily large amounts of propoxyphene for such patients.**

Drug Dependence—Propoxyphene can produce drug dependence characterized by psychic dependence and, less frequently, physical dependence and tolerance. Propoxyphene will only partially suppress the withdrawal syndrome in individuals physically dependent on morphine or other narcotics. The abuse liability of propoxyphene is qualitatively similar to that of codeine although quantitatively less, and propoxyphene should be prescribed with the same degree of caution appropriate to the use of codeine.

Usage in Ambulatory Patients—Propoxyphene may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery. The patient should be cautioned accordingly.

Usage in Pregnancy—Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, propoxyphene should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

Usage in Children—Propoxyphene is not recommended for use in children because documented clinical experience has been insufficient to establish safety and a suitable dosage regimen in the pediatric age group.

Salicylates should be used with extreme caution in the presence of peptic ulcer or coagulation abnormalities.

Precautions: Confusion, anxiety, and tremors have been reported in a few patients receiving propoxyphene concomitantly with orphenadrine.

Phenacetin has been reported to damage the kidneys when taken in large amounts for a long time.

Adverse Reactions: The most frequent adverse reactions are dizziness, sedation, nausea, and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include constipation, abdominal pain, skin rashes, lightheadedness, headache, weakness, euphoria, dysphoria, and minor visual disturbances.

The chronic ingestion of propoxyphene in doses exceeding 800 mg. per day has caused toxic psychoses and convulsions.

Administration and Dosage: A narcotic prescription is not required.

Darvon Compound-65 is given orally. The usual dosage is 1 Pulvule® (containing 65 mg. propoxyphene hydrochloride, 227 mg. aspirin, 162 mg. phenacetin, and 32.4 mg. caffeine) every four hours as needed for pain. [060576A]

Additional information available to the profession on request from Eli Lilly and Company Indianapolis, Indiana 46206

Lilly

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Carolina, Puerto Rico 00630

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